

SEP 12 2006

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Sara Carter  
Signature

09/12/2006  
Date

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

IN RE APPLICATION OF

Examiner:

**TSAO, ET AL.**

**OGDEN, Jr., Necholus**

APPLICATION NO: 10/722,008

Art Unit: **1751**

FILED: **November 25, 2003**

FOR: **LENS CARE COMPOSITION AND METHOD**

Commissioner for Patents  
Alexandria, Virginia 22313

**PETITION TO WITHDRAW HOLDING OF ABANDONMENT**

Dear Sir:

Applicants petition a withdrawal of the holding of Abandonment dated July 12, 2006, on the basis that Applicants filed a timely response. A reply to the Office Action dated January 4, 2006, was deposited with the US Postal Service on July 5, 2006 with a request for a three month extension. This reply was timely as the previous day, July 4, 2006, was a federal holiday. This reply contained a Certificate of Mailing signed by Ms. Ann Brayley and is attached hereto as Attachment A.

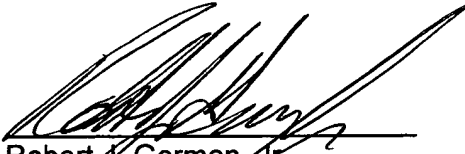
A postcard accompanying the reply indicating a mail date of July 5, 2006 was stamped as received by the OIPE on July 10, 2006 and returned to the Applicant. A copy of this postcard is attached hereto as Attachment B.

Furthermore, a statement based upon her personal knowledge attesting to the timely mailing of this reply is made Ms. Brayley. This statement is attached hereto as Attachment C.

Accordingly, Applicants request that the holding of Abandonment dated July 12, 2006 be withdrawn on the basis that a reply to the Office Action dated January 4, 2006 was timely filed.

Should the Examiner believe that a discussion with Applicants' representative would further the prosecution of this application, the Examiner is respectfully invited to contact the undersigned. Please address all correspondence to Robert Gorman, CIBA Vision, Patent Department, 11460 Johns Creek Parkway, Duluth, GA 30097. The Commissioner is hereby authorized to charge any other fees which may be required under 37 C.F.R. §§1.16 and 1.17, or credit any overpayment, to Deposit Account No. 50-2965.

Respectfully submitted,



Robert J. Gorman, Jr.  
Reg. No. 41,788  
(678) 415-4389

Date: September 12, 2006

CIBA Vision  
Patent Department  
11460 Johns Creek Parkway  
Duluth, GA 30097

SEP 10 2003

CASE LP/V-32800/A

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF

Examiner:

**TSAO, ET AL.**

**OGDEN, Jr., Necholas**

APPLICATION NO: 10/722,008

Art Unit: 1751

FILED: **November 25, 2003**

FOR: **LENS CARE COMPOSITION AND METHOD**

Commissioner for Patents  
Alexandria, Virginia 22313

**STATEMENT OF ANN BRAYLEY**

1. My name is Ann Brayley. I have obtained the age of majority and have personal knowledge of the statements herein.
2. I am the signatory of the Certificate of Mailing contained on the first page of the paper entitled, "Amendment A" attached hereto as Attachment A.
3. The date on said Certificate of Mailing is true and correct. Namely, I caused the response to the Office Action dated January 4, 2006 to be deposited with the United States Postal Service on July 5, 2006 with sufficient postage as first class mail in an envelope addressed to the Commissioner of Patents, Alexandria, Virginia 22313.
4. I certify the above to be complete and accurate according to my personal knowledge.

  
Ann Brayley

Date: 9/12/06

SEP 12 2006

CASE LP/V-32800/A

**CERTIFICATE OF MAILING**

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to the: Commissioner for Patents, Alexandria, Virginia 22313.

Ann Brayley  
Type or print name

Ann Brayley 7/5/06  
Signature Date

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

**IN RE APPLICATION OF**

**Examiner:**

**TSAO, ET AL.**

**OGDEN, Jr., Necholus**

**APPLICATION NO: 10/722,008**

**Art Unit: 1751**

**FILED: November 25, 2003**

**FOR: LENS CARE COMPOSITION AND METHOD**

Commissioner for Patents  
Alexandria, Virginia 22313

**AMENDMENT A**

JUL 7

Dear Sir:

The Office Action dated January 4, 2006 from Examiner Necholus Ogden, Jr. of Art Unit 1751 has been received and reviewed. The following is in response thereto.

# **CLAIM AMENDMENTS**

Please amend the claims as follows.

1. (Currently Amended) An aqueous contact lens disinfecting solution comprising a buffer and less than 1 ppm of a polymeric antimicrobial agent;  
wherein said solution has a tonicity of 200 to 450 mOsm/kg, a pH of between 6 and 8, ~~and a concentration of chloride ions below 1500 ppm; and~~  
wherein the buffer is a phosphate buffer at a concentration less than 0.1%, and the total concentration of chloride ions and phosphate ions below 1500 ppm.
2. (Canceled)
3. (Original) An aqueous contact lens disinfecting solution as claimed in Claim 1, wherein said polymeric antimicrobial agent is PHMB.
4. (Original) An aqueous contact lens disinfecting solution as claimed in Claim 3, wherein the concentration of said PHMB is less than or equal to 0.5 ppm.
5. (Original) An aqueous contact lens disinfecting solution as claimed in Claim 4, wherein said solution will result in at least a 1 log reduction in *C. albicans* within 15 minutes of contact.
6. (Original) An aqueous contact lens disinfecting solution as claimed in Claim 3, wherein the concentration of said PHMB is less than or equal to 0.25 ppm.
7. (Original) An aqueous contact lens disinfecting solution as claimed in Claim 6, wherein said solution will result in at least at least a 1.5 log reduction in *C. albicans* within 15 minutes of contact.
8. (Original) An aqueous contact lens disinfecting solution as claimed in Claim 1, further comprising a tonicity agent selected from the group consisting of non-halide containing electrolytes, non-electrolytic compounds, and mixtures thereof; wherein the majority of the tonicity of the solution is provided by said tonicity agent
9. (Original) An aqueous contact lens disinfecting solution as claimed in Claim 8, wherein said tonicity agent is sorbitol.
10. (Original) An aqueous contact lens disinfecting solution as claimed in Claim 9, the sorbitol is present in an amount of at least 2%, by weight, of said solution.
11. (Canceled)
12. (Currently Amended) An aqueous contact lens disinfecting solution as claimed in Claim 1 ~~44~~, wherein said phosphate buffer concentration is less than 0.06%.
13. (Original) An aqueous contact lens disinfecting solution as claimed in Claim 12, wherein said phosphate buffer concentration is from 0.005% to 0.015%.
14. (Original) An aqueous contact lens disinfecting solution as claimed in Claim 1, further comprising at least one surface-active agent.

15. (Original) An aqueous contact lens disinfecting solution as claimed in Claim 14, wherein said solution contains both tyloxapol and a poloxamer.
16. (Original) An aqueous contact lens disinfecting solution as claimed in Claim 1, further comprising dextranthenol.
17. (Original) An aqueous contact lens disinfecting solution as claimed in Claim 1, further comprising a chelating agent.
18. (Original) An aqueous contact lens disinfecting solution as claimed in Claim 17, wherein said chelating agent is EDTA.
19. (Original) An aqueous contact lens disinfecting solution as claimed in Claim 1, further comprising a viscosity enhancing agent.
20. (Original) An aqueous contact lens disinfecting solution as claimed in Claim 19, wherein said viscosity enhancing agent is PVP.
21. (Original) An aqueous contact lens disinfecting solution comprising:
  - (a) less than 1 ppm PHMB;
  - (a) 0.005% to 1% dextranthenol;
  - (b) 0.005% to 1% surface active agent;
  - (c) less than 0.06% phosphate buffer;
  - (d) less than 0.2% chelating agent;
  - (e) 0.01% to 1% viscosity enhancing agent; and
  - (f) at least 1% of a tonicity agent selected from the group consisting of glycerol, urea, propylene glycol, sodium bicarbonate, sugars, alcohols, polyols, and mixtures thereof;wherein said solution has a tonicity of 200 to 450 mOsm/kg, a pH of between 6 and 8, and a concentration of chloride ions below 1000 ppm.
22. (Original) An aqueous contact lens disinfecting solution as claimed in Claim 21, wherein said surface active agent selected from the group consisting of tyloxapol, polaxamers, and mixtures thereof; said chelating agent is EDTA; said viscosity enhancing agent is PVP; and said tonicity agent is sorbitol.
23. (Original) An aqueous contact lens disinfecting solution as claimed in Claim 21, comprising:
  - (a) less than 0.5 ppm PHMB;
  - (b) 0.01% to 0.1% dextranthenol;
  - (c) 0.001% to 0.5% surface active agent;
  - (d) 0.001% to 0.05% phosphate buffer;
  - (e) 0.1% to 0.3% viscosity enhancing agent; and
  - (f) at least 4% of a tonicity agent selected from the group consisting of glycerol, urea, propylene glycol, sodium bicarbonate, sugars, alcohols, polyols, and mixtures thereof;

wherein said solution has a tonicity of 200 to 450 mOsm/kg, a pH of between 6 and 8, and a concentration of chloride ions below 500 ppm.

24. (Original) An aqueous contact lens disinfecting solution as claimed in Claim 23, wherein said surface active agent selected from the group consisting of tyloxapol, polaxamers, and mixtures thereof; said chelating agent is EDTA; said viscosity enhancing agent is PVP; and said tonicity agent is sorbitol.

25. (Withdrawn) A method for cleaning and disinfecting a contact lens comprising contacting said contact lens with an aqueous solution comprising a buffer and less than 1 ppm of a polymeric antimicrobial agent; wherein said solution has a tonicity of 200 to 450 mOsm/kg, a pH of between 6 and 8, and a concentration of chloride ions below 1500 ppm.

26. (Withdrawn) An method as claimed in Claim 25, wherein said polymeric antimicrobial agent is PHMB.

27. (Withdrawn) An method as claimed in Claim 26, wherein the concentration of said PHMB is less than or equal to 0.5 ppm.

28. (Withdrawn) An method as claimed in Claim 27, wherein said method results in at least at least a 1 log reduction in *C. albicans* upon the lens within 15 minutes of contact.

29. (Withdrawn) An method as claimed in Claim 26, wherein the concentration of said PHMB is less than or equal to 0.25 ppm.

30. (Withdrawn) An method as claimed in Claim 29, wherein said method results in at least at least a 1.5 log reduction in *C. albicans* upon the lens within 15 minutes of contact.

**REMARKS*****Affirmation of Election***

Applicants affirm the provisional election made by Jian Zhou on November 3, 2005 to prosecute the invention of Group I, Claims 1 – 24.

***Remaining Claims***

Claims 2 and 11 have been canceled and Claims 1 and 12 have been amended to more clearly point out and distinctly claim the invention. Claims 2 and 11 have been canceled. After these amendments are entered, twenty-two (22) claims (Claims 1, 3 – 10, and 12 – 24) remain under consideration in this application.

***Claim Rejections under 35 U.S.C §102(e)/ §103 – Schwind, et al.***

Claims 1 – 12, 14, 16 – 19, 21, and 23 stand rejected under 35 USC §102(b) as being anticipated by or, in the alternative, under 35 USC §103, as obvious over *Schwind, et al.* (WO 2002/0155961). Specifically, Examiner cites paragraphs 0030 – 0032 and 0039 as teaching the claimed invention.

Claim 1 has been amended to incorporate the limitations of Claims 2 and 12. Specifically, Claim 1 has been amended to require a phosphate buffered lens care solution with a total concentration of chloride ions and phosphate ions below 1500 ppm. Additionally, the phosphate buffer is at a concentration less than 0.1%.

*Schwind, et al.* neither teach or suggest such a lens care composition. The paragraphs cited by the Examiner (and, more importantly, the document when read as a whole) do not teach a solution having less than 0.1% phosphate buffer, less than 1 ppm of a polymeric antimicrobial, and a total concentration of chloride ions and phosphate ions below 1500 ppm – all as required by Claim 1.

Specifically, neither the solution put forward at paragraphs 0030 – 0032 nor the reference as a whole make no teaching of the concentration of the buffer or the level of chloride and phosphate ions in the solution. Likewise, the solution put forward at paragraph 0039 does not have less than 1 ppm of a polymeric antimicrobial and has 8.6 g/l sodium chloride (resulting in approximately 5200 ppm chloride ion). This high level of chloride ion is explicitly taught by the present application to be avoided and not to be within the scope of the claimed invention (See, e.g., page 8, lines 7 – 14).

Furthermore, *Schwind, et al.* never teach or suggest that the total concentration of chloride and phosphate ions in the solution must be below 1500 ppm. This is important to note in view of the teachings of the present application at page 7, line 17 – page 8, line 5; that the level of chloride and phosphate ions in solutions can be affected by the method employed in the art of adjusting pH with hydrochloric acid and using TRIS·HCl buffer, rather than the “free-base” form that does not



include HCl. Because *Schwind, et al.* make no teachings or suggestions of this level of ions, it cannot anticipate or render obvious Claim 1.

Claims 2 and 12 are canceled. Claims 3 – 11, 14, and 16 – 19 depend from Claim 1 and likewise, cannot be anticipated or rendered obvious by *Schwind, et al.* Claims 21 and 23 further claim a phosphate buffer that is lower than 0.06% (Claim 21) or between 0.001 and 0.05% (Claim 23). These levels of phosphate buffer are not taught or suggested by *Schwind, et al.* Accordingly, Applicants respectfully request that this rejection be withdrawn.

***Claim Rejections under 35 U.S.C §102(e)/ §103 – Groemminger, et al.***

Claims 1 – 8, 11 – 12, 14 – 15, and 17 – 20 stand rejected under 35 USC §102(b) as being anticipated by or, in the alternative, under 35 USC §103, as obvious over *Groemminger, et al.* (US 6,872,695).

As explained above, Claim 1 has been amended to incorporate the limitations of Claims 2 and 12. Specifically, Claim 1 has been amended to require a phosphate buffered lens care solution with a total concentration of chloride ions and phosphate ions below 1500 ppm. Additionally, the phosphate buffer is at a concentration less than 0.1%.

*Groemminger, et al.* neither teach or suggest such a lens care composition. Specifically, *Groemminger, et al.* do not teach the use of a phosphate buffer at any level. In fact, the solutions of the cited reference are not buffered at all.

Furthermore, *Groemminger, et al.* also do not teach or suggest that the total concentration of chloride and phosphate ions in the solution must be below 1500 ppm. Because *Groemminger, et al.* make no teachings or suggestions of this level of ions, it cannot anticipate or render obvious Claim 1.

Claims 2 and 12 are canceled. Claims 3 – 8, 11, 14, and 17 – 19 depend from Claim 1 and likewise, cannot be anticipated or rendered obvious by *Schwind, et al.* Accordingly, Applicants respectfully request that this rejection be withdrawn.

***Claim Rejections under 35 U.S.C §103 – Schwind, et al. in view of Hu, et al.***

Claim 15 stands rejected under 35 USC §103(a) as being unpatentable over *Schwind, et al.* (WO 2002/0155961) in view of *Hu, et al.* (US 6,037,328).

Claim 15 is dependent from Claim 1. With regard to Claim 1, *Schwind, et al.* has been discussed above. *Hu, et al.* do not provide further teachings that would render the invention claimed in Claim 1 obvious. Accordingly, Applicants respectfully request that this rejection be withdrawn.

***Claim Rejections under 35 U.S.C §103 – Schwind, et al. in view of Groemminger, et al.***

Claims 20, 22, and 24 stand rejected under 35 USC §103(a) as being unpatentable over *Schwind, et al.* (WO 2002/0155961) in view of *Groemminger, et al.* (US 6,872,695).

Claim 20 is dependent from Claim 1; Claim 22 is dependent from Claim 21; and Claim 24 is dependent from Claim 23. With regard to Claims 1, 21, and 23, *Schwind, et al.* has been discussed above. *Groemminger, et al.* do not provide further teachings that would render the invention claimed in Claim 1, 21, and 23 obvious. Accordingly, Applicants respectfully request that this rejection be withdrawn.

***Double Patenting Rejections***

Claims 1 – 24 stand rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over Claims 1 – 4 of 6261546; Claims 1 – 15 of 5858996; Claims 1 – 12 of 5846919; Claims 1 – 5 of 5807585; Claims 1 – 5 of 5683993; Claims 1 – 11 of 5576276;

None of these references claim the currently claimed lens care composition. The references do not teach a solution having less than 0.1% phosphate buffer, less than 1 ppm of a polymeric antimicrobial, and a total concentration of chloride ions and phosphate ions below 1500 ppm – all as required by Claims 1 - 24.

**CONCLUSION**

In view of the foregoing and in conclusion, Applicants submit that all of the pending claims are now in conditions for allowance.

Should the Examiner believe that a discussion with Applicants' representative would further the prosecution of this application, the Examiner is respectfully invited to contact the undersigned. Please address all correspondence to Robert Gorman, CIBA Vision, Patent Department, 11460 Johns Creek Parkway, Duluth, GA 30097. The Commissioner is hereby authorized to charge any other fees which may be required under 37 C.F.R. §§1.16 and 1.17, or credit any overpayment, to Deposit Account No. 50-2965.

Respectfully submitted,



Robert J. Gorman, Jr.  
Reg. No. 41,789  
(678) 415-4389

Date: July 5, 2006

CIBA Vision  
Patent Department  
11460 Johns Creek Parkway  
Duluth, GA 30097

SEP 18 2006

CASE CLV-32800A

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Sara Carter  
Type or print name

  
Signature

July 05, 2006  
Date

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF

TSAO ET AL.

APPLICATION NO: 10/722,008

FILED: NOVEMBER 25, 2003

FOR: LENS CARE COMPOSITION AND METHOD

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

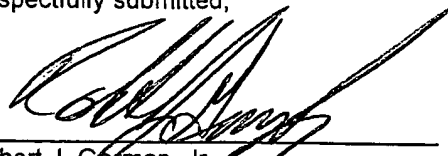
PETITION FOR EXTENSION OF TIME

Sir:

The Office Action of January 4, 2006 has a shortened statutory time set to expire on April 4, 2006. A three-month extension is hereby requested pursuant to 37 CFR §1.136(a).

Please charge Deposit Account No. 50-2965 in the name of Ciba Vision in the amount of \$1020 for payment of the extension fee. An additional copy of this paper is here enclosed. The Commissioner is hereby authorized to charge any additional fees under 37 CFR §1.17 which may be required, or credit any overpayment, to Account No. 50-2965 in the name of Ciba Vision.

Respectfully submitted,



Robert J. Gorman, Jr.  
Attorney for Applicants  
Reg. No. 41,789  
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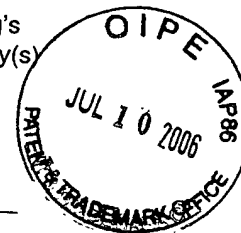
Date: July 05, 2006

SEP 13 2006

Case No. CL/V-32800A  
Application No. 10/722,008  
Mailing Date: July 05, 2006  
Due Date: April 04, 2006  
Express Mail No. \_\_\_\_\_

The Patent & Trademark Office acknowledges, and has stamped  
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☐ Applic. Filing Papers - Fee \$ \_\_\_\_\_  
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    ☐ Provisional Application  
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☐ Executed/Unexecuted Decl. - Fee \$ \_\_\_\_\_  
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☐ Preliminary Amendment \_\_\_\_\_ Pg's  
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